EXHIBIT A

Supreme Court of Pennsylvania

Court of Common Pleas
Civil Cover Sheet

ALLEGHENY County

For Prothonotary Use Only:	TIME STAMP
Docket No:	

The information collected on this form is used solely for court administration purposes. This form does not supplement or replace the filing and service of pleadings or other papers as required by law or rules of court.

SECTION A

Commencement of Action:
☒ Complaint ☐ Writ of Summons ☐ Petition
☐ Transfer from Another Jurisdiction ☐ Declaration of Taking

Lead Plaintiff's Name:	Lead Defendant's Name:
ROXANNE BLEAKNEY	PHILIPS RS NORTH AMERICA LLC
Are money damages requested? ☒ **Yes** ☐ **No**	Dollar Amount Requested: (check one) ☐ within arbitration limits ☒ outside arbitration limits
Is this a *Class Action Suit*? ☒ **Yes** ☐ **No**	**Is this an *MDJ Appeal*?** ☐ **Yes** ☒ **No**

Name of Plaintiff/Appellant's Attorney: Kevin Tucker, East End Trial Group LLC, ktucker@eastendtrialgroup.com

☐ **Check here if you have no attorney (are a Self-Represented [Pro Se] Litigant)**

SECTION B

Nature of the Case: Place an "X" to the left of the **ONE** case category that most accurately describes your ***PRIMARY CASE***. If you are making more than one type of claim, check the one that you consider most important.

TORT (*do not include Mass Tort*)
- ☐ Intentional
- ☐ Malicious Prosecution
- ☐ Motor Vehicle
- ☐ Nuisance
- ☐ Premises Liability
- ☐ Product Liability *(does not include mass tort)*
- ☐ Slander/Libel/ Defamation
- ☒ Other: Unfair Trade Practices

MASS TORT
- ☐ Asbestos
- ☐ Tobacco
- ☐ Toxic Tort - DES
- ☐ Toxic Tort - Implant
- ☐ Toxic Waste
- ☐ Other:

PROFESSIONAL LIABLITY
- ☐ Dental
- ☐ Legal
- ☐ Medical
- ☐ Other Professional:

CONTRACT (*do not include Judgments*)
- ☐ Buyer Plaintiff
- ☐ Debt Collection: Credit Card
- ☐ Debt Collection: Other
- ☐ Employment Dispute: Discrimination
- ☐ Employment Dispute: Other
- ☐ Other:

REAL PROPERTY
- ☐ Ejectment
- ☐ Eminent Domain/Condemnation
- ☐ Ground Rent
- ☐ Landlord/Tenant Dispute
- ☐ Mortgage Foreclosure: Residential
- ☐ Mortgage Foreclosure: Commercial
- ☐ Partition
- ☐ Quiet Title
- ☐ Other:

CIVIL APPEALS
Administrative Agencies
- ☐ Board of Assessment
- ☐ Board of Elections
- ☐ Dept. of Transportation
- ☐ Statutory Appeal: Other
- ☐ Zoning Board
- ☐ Other:

MISCELLANEOUS
- ☐ Common Law/Statutory Arbitration
- ☐ Declaratory Judgment
- ☐ Mandamus
- ☐ Non-Domestic Relations Restraining Order
- ☐ Quo Warranto
- ☐ Replevin
- ☐ Other:

IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA

ROXANNE BLEAKNEY and CARL BLEAKNEY, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

PHILIPS RS NORTH AMERICA LLC,

Defendant.

CIVIL DIVISION

No.

CLASS ACTION

CLASS ACTION COMPLAINT

Filed on behalf of Plaintiffs:
Roxanne Bleakney and Carl Bleakney

Counsel of record for Plaintiffs:

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Other Attorneys On Signature

IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA

ROXANNE BLEAKNEY and CARL BLEAKNEY, individually and on behalf of all others similarly situated,	CIVIL DIVISION No.
Plaintiffs,	CLASS ACTION
v.	
PHILIPS RS NORTH AMERICA LLC,	
Defendant.	

NOTICE TO DEFEND

YOU HAVE BEEN SUED IN COURT. If you wish to defend against the claims set forth in the following pages, you must take action within **TWENTY (20)** days after this Complaint and Notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the Complaint or for any claim or relief requested by the Plaintiffs. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

LAWYER REFERRAL SERVICE
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IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA

ROXANNE BLEAKNEY and CARL BLEAKNEY, individually and on behalf of all others similarly situated,	CIVIL DIVISION No.
Plaintiffs,	CLASS ACTION
v.	
PHILIPS RS NORTH AMERICA LLC,	
Defendant.	

CLASS ACTION COMPLAINT

Plaintiffs Roxanne Bleakney and Carl Bleakney, individually and on behalf of all others similarly situated, bring this action against Defendant Philips RS North America LLC ("Philips") and allege the following based on personal knowledge, information and belief, and the investigation of counsel.

NATURE AND SUMMARY OF THE ACTION

1. Plaintiffs bring this action on behalf of themselves and a proposed class of purchasers and users of Continuous Positive Airway Pressure (CPAP) and Bi-Level Positive Airway Pressure (Bi-Level PAP) devices and mechanical ventilators manufactured by Philips, which contain polyester-based polyurethane sound abatement foam ("PE-PUR Foam").

2. On April 26, 2021, Philips made a public announcement disclosing it had determined there were risks that the PE-PUR Foam used in certain CPAP, Bi-Level PAP, and mechanical ventilator devices it manufactured may degrade or off-gas under certain circumstances.

3. On June 14, 2021, Koninklijke Philips N.V. ("Royal Philips") issued a recall in the United States of its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam, because Philips had determined that (a) the PE-PUR Foam was at risk for degradation into

particles that may enter the devices' pathway and be ingested or inhaled by users, and (b) the PE-PUR Foam may off-gas certain chemicals during operation. *See* Philips Recall Notice attached hereto as Exhibit "A."

4. Philips further disclosed in its Recall Notice that "these issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment." *Id.*

5. Philips has disclosed that the absence of visible particles in the devices does not mean that PE-PUR Foam breakdown has not already begun. Philips reported that lab analysis of the degraded foam reveals the presence of harmful chemicals, including: Toluene Diamine ("TDA"), Toluene Diisocyanate ("TDI"), and Diethylene Glycol ("DEG").[1]

6. Prior to issuing the Recall Notice, Philips received complaints regarding the presence of black debris/particles within the airpath circuit of its devices (extending from the device outlet, humidifier, tubing, and mask). Philips also received reports of headaches, upper airway irritation, cough, chest pressure and sinus infection from users of these devices.

7. In its Recall Notice, Philips disclosed that the potential risks of particulate exposure to users of these devices include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing of PE-PUR Foam in these devices include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

[1] Philips, *Sleep and Respiratory Care Update; Clinical information for physicians*, June 14, 2021, https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (last visited Aug. 2, 2021).

8. Philips recommended that patients using the recalled CPAP and Bi-Level PAP devices immediately discontinue using their devices and that patients using the recalled ventilators for life-sustaining therapy consult with their physicians regarding alternative ventilator options.

9. In 2018, Plaintiffs purchased a DreamStation Auto BiPAP machine that Mr. Bleakney has used nightly since.

10. In 2021, Plaintiffs learned their Philips' DreamStation Auto BiPAP device may be subject to a recall due to the presence of a dangerous PE-PUR Foam that could cause Mr. Bleakney to suffer from adverse health effects, including, *inter alia*, cancer and organ failure.

11. Plaintiffs were advised to verify whether Mr. Bleakney's device was subject to the recall by submitting its serial number to an online database Philips established.

12. Plaintiffs received confirmation from Philips' online database that Mr. Bleakney's DreamStation Auto BiPAP device was subject to recall.

13. Because immediately stopping his use of the DreamStation would pose a serious medical risk, Mr. Bleakney was advised to continue using his recalled DreamStation until Plaintiffs received a replacement from Philips' recall program or until Plaintiffs purchased their own replacement.

14. Because Philips has failed to replace the recalled DreamStation in a timely manner, Plaintiffs are planning to purchase a replacement on their own. Plaintiffs are budgeting approximately $2,500 for this replacement.

15. Plaintiffs have incurred substantial expenses related to Mr. Bleakney's DreamStation Auto BiPAP device that Plaintiffs would not have incurred had they known of the adverse health effects described above because Plaintiffs would not have purchased the

DreamStation Auto BiPAP device and the equipment used with it had they known of these adverse health effects.

16. In addition, Mr. Bleakney has experienced chest tightness and respiratory irritants during his use of the Philips' DreamStation Auto BiPAP device. Since being notified of the recall, Mr. Bleakney has experienced anxiety concerning the potential serious health risks he is facing from possible exposure to offgassed or degraded PE-PUR Foam in the recalled device.

17. Plaintiffs seek to recover damages based on, inter alia, Philips' breach of express warranty, breach of implied warranties, misrepresentations, omissions, and breach of Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), 73 P.S. §§ 201-1-201-9.2 in connection with Philips' manufacture, marketing and sales of devices containing PE-PUR Foam on behalf of themselves and the proposed Classes.

18. In addition, Plaintiffs seeks medical monitoring damages for users of Philips' devices identified in the Recall Notice, who are at risk of suffering from serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic affects.

PARTIES

19. Plaintiff Roxanne Bleakney is a natural person over the age of eighteen. She resides in Pennsylvania.

20. Plaintiff Carl Bleakney is a natural person over the age of eighteen. He resides in Pennsylvania.

21. Defendant Philips is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips is a wholly-owned

subsidiary of Royal Philips. Philips was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.[2]

JURISDICTION AND VENUE

22. The Court has subject matter jurisdiction under 42 Pa. C.S. § 931.

23. The Court has personal jurisdiction over Philips under 42 Pa. C.S. § 5301.

24. Venue is proper under Pa. R. Civ. P. 2179 because Philips regularly conducts business in this County and/or this is the County where the transactions or occurrences took place out of which the cause of action arose.

JURISDICTION AND VENUE

I. Continuous Positive Airway Pressure Therapy

25. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a hose and a nasal or facemask device that delivers constant and steady air pressure to an individual's throat to help individuals breathe.

26. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep

[2] *Philips announces completion of tender offer to acquire Respironics*, WEB WIRE, https://www.webwire.com/ViewPressRel.asp?aId=61199 (last visited Aug. 2, 2021).

apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

II. Bi-Level Positive Airway Pressure Therapy

27. Bi-Level Positive Airway Pressure ("BiPAP") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway.

28. BiPAP therapy is distinguishable from CPAP therapy, however, because Bi-Level PAP devices deliver two alternating levels—inspiratory and expiratory—of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device.

29. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. Bi-Level PAP devices deliver one level of pressurize air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

III. Mechanical Ventilation

30. Mechanical ventilation is a treatment to help a person breathe when they find it difficult or are unable to breathe on their own.

31. A mechanical ventilator pushes airflow into the patient's lungs to help them breathe. Mechanical ventilation may be invasive ventilation with a tube inserted into the patient's airway, performed in the intensive care unit in the hospital or a long-term institutional setting.

32. Non-invasive ventilation can be used at home by people with respiratory difficulties.

SUBSTANTIVE ALLEGATIONS

33. Philips developed, marketed, and sold a variety of CPAP and Bi-Level PAP respirator devices and mechanical ventilators under its "Sleep & Respiratory Care" segment of its business designed to assist individuals with a number of sleep, breathing, and respiratory conditions, including obstructive sleep apnea, central sleep apnea, complex sleep apnea syndrome, and Chronic Obstructive Pulmonary Disease (COPD), as well as to assist those individuals requiring invasive and non-invasive ventilators for acute and sub-acute hospital environments.

34. Philips' CPAP and Bi-Level PAP respirator devices and its mechanical ventilators typically cost several hundred, if not thousands of dollars.

35. Philips has sold millions of these devices in the United States.

I. Philips Sleep & Respiratory Care Devices Endangered Users

36. On April 26, 2021, in its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led to a discovery that the type of PE-PUR Foam Philips used to minimize noise in several CPAP and Bi Level PAP respirators and mechanical ventilators posed health risks to its users.

37. Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone[], and certain environmental conditions involving high humidity and temperature."[3]

[3] *First Quarter Results*, Philips (Apr. 26, 2021), https://www.results.philips.com/publications/q121/downloads/pdf/en/philips-first-quarter-results-2021-report.pdf (last visited Aug. 2, 2021).

38. Seven weeks later, on June 14, 2021, Philips announced a recall of numerous models of CPAP and Bi-Level PAP devices, as well as a variety of its mechanical ventilators "to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices."[4]

39. Philip announced that it had determined that the "PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals."[5]

40. In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.[6]

41. The list of the devices recalled by Philips (the "Recalled Devices") include:

Philips CPAP and Bi-Level PAP Devices Manufactured Before April 26, 2021 Subject to Recall[7]	
Device Name/Model Type	**Type**
• E30 (Emergency Use Authorization)	Continuous ventilator; minimum ventilatory support, facility use
• DreamStation ASK	Continuous ventilator; non-life supporting

[4] *Philips issues recall notification* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices*, PHILIPS (June 14, 2021), https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (last visited Aug. 2, 2021).

[5] *Id.*

[6] Associated Press, *Philips recalls ventilators, sleep apnea machines due to health risks*, NBC NEWS, https://www.nbcnews.com/business/consumer/philips-recalls-ventilators-sleep-apnea-machines-duehealth-risks-n1270725 (last visited Aug. 2, 2021).

[7] Recall Notice (Exhibit "A" hereto); *see also* Medical Device recall notification (U.S. only) / field safety notice (International Markets), PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed Aug. 2, 2021); Royal Philips Update on the recall notification, https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (last Aug. 2, 2021).

• DreamStation ST, AVAPS • SystemOne ASV4 • C Series ASV • C Series S/T and AVAPS • OmniLab Advanced Plus	
• SystemOne (Q Series) • DreamStation • DreamStation GO • Dorma 400 • Dorma 500 • REMStar SE Auto	Non-continuous Ventilator
Philips Mechanical Respirator Devices Manufactured Before April 26, 2021 Subject to Recall[8]	
Device Name/Model Type	**Type**
• Trilogy 100 Ventilator • Trilogy 200 Ventilator • Garbin Plus, Aeris, LifeVent Ventilator	Continuous ventilator
• A-Series BiPAP Hybrid A30 • Philips A-Series BiPAP V30 Auto	Continuous ventilator, minimum ventilatory support, facility use
• Philips A-Series BiPAP A40 • Philips A-Series BiPAP A30	Continuous ventilator, non-life supporting

42. According to Philips, the PE-PUR Foam used in Recalled Devices puts users at risk of suffering from: "[i]rritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.* kidneys and liver) and toxic carcinogenic affects."[9]

43. Philips reported to physicians that PE-PUR Foam particles "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve."

44. Further, Philips reported that "based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact,

[8] *Id.*
[9] *Id.*

from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment."

45. Philips announced that it has received reports of specific complaints from users of Recalled Devices who suffered from "headache[s], upper airway irritation, cough, chest pressure and sinus infection."[10]

II. The Health Risks Associated with Use of the Recalled Devices Renders Them Worthless

46. As a result of the health risks associated with the use of the Recalled Devices, together with Philips' concealment of these risks from the date they were first reported to Philips' or discovered by Philips through April 26, 2021, the Recalled Devices have been rendered completely worthless or, at the very least, have been substantially diminished in value.

47. The information described above, including the now-known health risks of Philips' CPAP devices, Bi-Level PAP devices and mechanical ventilators, the recall, and the medical warnings and advice issued by Philips, have rendered the Recalled Devices worthless to patients with sleep apnea and respiratory conditions.

48. Individuals not using life-supporting ventilators must immediately discontinue their use of the Recalled Devices or face serious health risks as grave as organ failure or cancer.

49. If they choose to discontinue use of the Recalled Devices they must pay for another expensive device in order to receive effective treatment for their sleep apnea and/or respiratory conditions.

50. Individuals using life-supporting ventilators must seek an alternative treatment before discontinuing use of the Recalled Devices.

[10] Recall Notice (Exhibit A hereto).

51. Recognizing this, Philips issued the following advice to patients using any of the Recalled Devices:

- "**For patients using BiLevel PAP and CPAP devices:** Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."[11]
- "**For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps.**"[12]

III. Philips Unreasonably Delayed its Recall

52. At no time prior to its Regulatory Update on April 26, 2021, did Philips disclose to purchasers or users of the Recalled Devices that the PE-PUR Foam contained therein may offgas or degrade upon use.

53. Prior to the Update, Philips did not disclose any health risks associated with use of the Recalled Devices.

54. Philips has not disclosed when they first discovered or received reports from users of their Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."[13]

55. At a minimum, as a result of user reports, Defendant was aware of the offgassing and degradation of the PE-PUR Foam used in the Recalled Devices at some point prior to the recall, yet continued to manufacture and sell the Recalled Devices with such awareness.

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[11] Medical Device recall notification (U.S. only) / field safety notice (International Markets), PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (last visited Aug. 2, 2021) (Questions and answers) (emphasis in original).

[12] *Id.*

[13] Recall Notice (Exhibit "A" hereto).

56. During this period, Defendant unreasonably and unjustly profited from the manufacture and sale of the Recalled Devices and unreasonably put users of the Recalled Devices at risk of development of serious adverse health effects, including organ failure and cancer.

IV. Plaintiffs Mr. and Mrs. Bleakney

57. Mr. and Mrs. Bleakney are residents of Pennsylvania.

58. In 2018, Plaintiffs purchased a Recalled Device, the DreamStation Auto BiPAP machine.

59. The manuals accompanying Plaintiffs' Respironics DreamStation device did not contain any language or warnings of health risks associated with use of the device, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects.

60. Had Philips informed Plaintiffs of these risks, they would not have purchased and Mr. Bleakney would not have used the Recalled Device.

61. Without knowing of the health risks associated with use of the Recalled Devices, Mr. Bleakney used the DreamStation regularly to treat his atrial flutter and sleep apnea.

62. Plaintiffs consulted Mr. Bleakney's doctor after learning of the health risks associated with the Recalled Devices.

63. Mr. Bleakney's doctor instructed him to buy a new Bi-Level PAP device, or continue using his current DreamStation because the alternative—not using any Bi-Level PAP machine—would be too great a risk to Mr. Bleakney's health.

64. Because Philips has failed to replace the recalled DreamStation in a timely manner, Plaintiffs are planning to purchase a replacement on their own. Plaintiffs are budgeting approximately $2,500 for this replacement.

65. Until then, Mr. Bleakney does not have any choice but to continue using his recalled DreamStation.

66. Still, Plaintiffs' DreamStation device is now worthless.

TOLLING AND ESTOPPEL

I. Discovery Rule Tolling

67. Plaintiffs and the Classes had no way of knowing about Philips' conduct with respect to the health risks associated with the use of the Recalled Devices.

68. Neither Plaintiffs nor any other members of the Class, through the exercise of reasonable care, could have discovered the conduct by Philips alleged herein.

69. Further, Plaintiff and members of the Classes did not discover and did not know of facts that would have caused a reasonable person to suspect that Philips was engaged in the conduct alleged herein.

70. For these, reasons, all applicable statutes of limitation have been tolled by the discovery rule with respect to claims asserted by Plaintiffs and the Classes.

II. Fraudulent Concealment Tolling

71. By failing to provide immediate notice of the adverse health effects associated with continued use of the Recalled Devices, Philips concealed its conduct and the existence of the claims asserted herein from Plaintiffs and the members of the Classes.

72. Upon information and belief, Philips intended its acts to conceal the facts and claims from Plaintiffs and members of the Classes.

73. Plaintiffs and the members of the Classes were unaware of the facts alleged herein without any fault or lack of diligence on their part and could not have reasonably discovered Philips' conduct.

74. For this reason, any statute of limitations that otherwise may apply to the claims of Plaintiffs or members of the Classes should be tolled.

CLASS ACTION ALLEGATIONS

75. Plaintiffs bring this action individually and on behalf of all others similarly situated under Rules 1702, 1708, and 1709 of the Pennsylvania Rules of Civil Procedure.

76. Plaintiffs seek to certify the following Classes:

> **Purchaser Class**: All Pennsylvania citizens who are domiciled in Pennsylvania and who purchased a CPAP, Bi-Level PAP, or Mechanical Ventilator device that was manufactured by Philips before April 26, 2021, and recalled by Philips on June 14, 2021.
>
> **User Class**: All Pennsylvania citizens who are domiciled in Pennsylvania and who purchased and used a CPAP, Bi-Level PAP, or Mechanical Ventilator device that was manufactured by Philips before April 26, 2021, and recalled by Philips on June 14, 2021.

77. Plaintiffs reserve the right to expand, narrow, or otherwise modify the Classes as the litigation continues and discovery proceeds.

78. Pa. R. Civ. P. 1702(1), 1708(a)(2): Each Class is so numerous that joinder of its Class Members is impracticable. Since each of the claims of the Class Members is substantially identical, and the Class Members request substantially similar relief, centralizing the Class Members' claims in a single proceeding likely is the most manageable litigation method available.

79. Pa. R. Civ. P. 1702(2), 1708(a)(1): Plaintiffs and each Member of each Class share numerous common questions of law and fact that will drive the resolution of the litigation and predominate over any individual issues. For example, there is a single common answer to the question of whether Defendant knew or should have known that the PE-PUR Foam used for sound abatement posed health risks. The answer to this question is the same for Plaintiffs and each Member of each Class, and Plaintiffs and each Member of each Class require the same proof to

answer this question. This question, and other common questions of law and fact, predominate over any individual issues.

80. Pa. R. Civ. P. 1702(3): Plaintiffs' claims are typical of the claims of each Member of each Class because the claims are based on the same legal theories and arise from the same conduct.

81. Pa. R. Civ. P. 1702(4), 1709: Plaintiffs are adequate representatives of each Member of each Class because the interests of Plaintiffs and each Member of each Class align. Plaintiffs will fairly, adequately, and vigorously represent and protect the interests of each Member of each Class and have no interest antagonistic to any Member of either Class. Plaintiffs retained counsel who are competent and experienced in the prosecution of class action litigation. Plaintiffs have or can acquire adequate financial resources to assure that the interests of each Member of each Class will not be harmed.

82. Pa. R. Civ. P. 1708(a)(3), (6), (7): Given the complexity and nature of the issues presented and the relief requested, the expense and time necessary to obtain such relief, and the anticipated recovery and relief that Plaintiffs and each Member of each Class may obtain, the class action mechanism is by far the preferred and most efficient litigation mechanism to adjudicate the claims of Plaintiffs and each Member of each Class. Additionally, requiring Plaintiffs and each Member of each Class to file individual actions would impose a crushing burden on the court system. Class treatment presents far fewer management difficulties and provides benefits of a single adjudication and economies of scale.

83. Pa. R. Civ. P. 1708(a)(4): Based on the knowledge of Plaintiffs and undersigned counsel, there are no similar cases seeking relief for a Pennsylvania-only class against Defendant.

84. Pa. R. Civ. P. 1708(a)(5): This forum is appropriate for this litigation, as Defendant regularly conducts business in this County and all or part of the claims arose in this County.

85. Class certification, therefore, is appropriate under Rules 1702, 1708, and 1709 of the Pennsylvania Rules of Civil Procedure because the above common questions of law or fact predominate over any questions affecting individual members of each Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

CLAIMS FOR RELIEF

COUNT I
BREACH OF EXPRESS WARRANTY
(on behalf of Plaintiffs and both Classes)

86. Plaintiffs incorporates the foregoing allegations as if fully set forth herein.

87. Philips marketed and sold the Recalled Devices into the stream of commerce with the intent that the Recalled Devices would be purchased by Plaintiffs and the Classes.

88. Philips expressly warranted, advertised, and represented to Plaintiffs and the Classes that the Recalled Devices were safe and appropriate for human use.

89. Philips made these express warranties regarding the Recalled Devices' quality and fitness for use in writing through its website, advertisements, and marketing materials, and on the Recalled Devices' packaging and labels.

90. These express warranties became part of the basis of the bargain that Plaintiffs and the Classes entered into upon purchasing the Recalled Devices.

91. Philips' advertisements, warranties, representations, and omissions regarding health risks associated with the Recalled Devices, were made in connection with the sale of the Recalled Devices to Plaintiff and the Classes.

92. Plaintiff and the Classes relied on Philips' advertisements, warranties, representations, and omissions regarding the Recalled Devices in deciding whether to purchase and use Philips' Recalled Devices.

93. Philips' Recalled Devices do not conform to Philips' advertisements, warranties, representations, and omissions in that they are not safe, healthy, and appropriate for human use, and pose risks of serious injury and disease, including organ failure and cancer.

94. Philips therefore breached its express warranties by placing Recalled Devices into the stream of commerce and selling them to consumers, when their use posed health risks, had dangerous effects and were unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by Philips.

95. These associated health effects substantially impair the use, value, safety of the Recalled Devices, and render them worthless.

96. Philips was aware, or should have been aware, of the toxic or dangerous health effects of the use of the Recalled Devices, but nowhere on the package labeling or package inserts or on Philips' websites or other marketing materials did Philips warn Plaintiffs and members of the Classes that they were at risk of developing adverse health effects as a result of the dangerous PE-PUR Foam used in the Recalled Devices.

97. Instead, Philips concealed the dangerous health effects of the PE-PUR Foam used in the Recalled Devices and deceptively represented that these products were safe, healthy, and appropriate for use.

98. Philips thus utterly failed to ensure that the material representations they were making to consumers were true.

99. The adverse health effects associated with use of the Recalled Devices existed when they left Philips' possession or control and were sold to Plaintiff and members of the Classes. The dangers associated with use of the Recalled Devices were undiscoverable by Plaintiff and members of the Classes at the time of purchase of the Recalled Devices.

100. As manufacturers, marketers, advertisers, distributors and sellers of the Recalled Devices, Philips had exclusive knowledge and notice of the fact that the Recalled Devices did not conform to the affirmations of fact and promises.

101. In addition, or in the alternative, to the formation of an express contract, Philips made each of the above-described representations and omissions to induce Plaintiffs and members of the Classes to rely on such representations and omissions.

102. Philips' affirmations of fact and promises and its omissions were material, and Plaintiffs and members of the Classes reasonably relied upon such representations and omissions in purchasing and using the Recalled Devices.

103. All conditions precedent to Philips' liability for its breach of express warranty have been performed by Plaintiffs or members of the Classes.

104. Affording Philips an opportunity to cure its breaches of written warranties would be unnecessary and futile here.

105. Philips was placed on reasonable notice from user reports and its lab testing that the PE-PUR Foam in the Recalled Devices was unsafe.

106. Philips had ample opportunity either to stop using the PE-PUR Foam or to replace the PE-PUR Foam in the Recalled Devices to make them safe and healthy for use by Plaintiffs and members of the Classes, but failed to do so until now.

107. As a direct and proximate result of Philips' breaches of express warranty, Plaintiffs and members of the Classes have been damaged because they did not receive the products as specifically warranted by Philips.

108. Plaintiffs and members of the Classes did not receive the benefit of the bargain and suffered damages at the point of sale stemming from their overpayment for the Recalled Devices.

109. Plaintiffs and the Classes seek actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for Philips' failure to deliver goods conforming to their express warranties and resulting breach.

COUNT II
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(on behalf of Plaintiffs and both Classes)

110. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

111. Philips are merchants engaging in the sale of goods to Plaintiff and the Classes.

112. There was a sale of goods from Philips to Plaintiffs and the Classes.

113. At all times mentioned herein, Philips manufactured or supplied the Recalled Devices, and prior to the time the Recalled Devices were purchased by Plaintiffs and the Classes, Philips impliedly warranted to them that the Recalled Devices were of merchantable quality, fit for their ordinary use, and conformed to the promises and affirmations of fact and omissions made on the Recalled Devices' labels and packaging, including that the Recalled Devices were safe and appropriate for human use.

114. Plaintiffs and the Classes relied on Philips' promises and affirmations of fact and omissions when they purchased and used the Recalled Devices.

115. Contrary to these representations and warranties, the Recalled Devices were not fit for their ordinary use and did not conform to Philips' affirmations of fact and promises and

omissions because use of the Recalled Devices is accompanied by the risk of adverse health effects, which does not conform to the labels and packaging of these devices.

116. Philips breached its implied warranties by selling Recalled Devices that failed to conform to the promises or affirmations of fact made on the packaging or label, as use of each Recalled Devices was accompanied by the risk of developing adverse health effects that do not conform to the packaging or label.

117. Philips was on notice of this breach, as it was made aware of the adverse health effects accompanying use of the Recalled Devices through user reports submitted to Philips and through lab testing.

118. Privity exists because Philips impliedly warranted to Plaintiffs and the Classes through the warranting, packaging, advertising, marketing, and labeling that the Recalled Devices were natural, and suitable for use to treat health conditions, and made no mention of the attendant health risks associated with use of the Recalled Devices.

119. As a direct and proximate result of Philips' conduct, Plaintiffs and the Classes have suffered actual damages in that each Recalled Device they purchased is worth less than the price they paid and which they would not have purchased at all had they known of the attendant health risks associated with the use of each Recalled Device.

120. Plaintiffs and the Classes seek actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for Philips' failure to deliver goods conforming to their implied warranties and resulting breach.

COUNT III
FRAUDULENT MISREPRESENTATION
(on behalf of Plaintiffs and both Classes)

121. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

122. Philips failed to advise Plaintiffs and the Classes that the Recalled Devices posed serious health risks to their users and Philips falsely represented to Plaintiffs and the Classes that the Recalled Devices were safe for human use.

123. Philips intentionally, knowingly, and recklessly made these misrepresentations and omissions to induce Plaintiffs and the Classes to purchase the Recalled Devices.

124. Philips knew that its representations and omissions about the Recalled Devices were false in that the Recalled Devices contained PE-PUR Foam and thus were at risk of causing adverse health effects to users of the Recalled Devices, which does not conform to the products' labels, packaging, advertising, and statements.

125. Philips knowingly allowed its packaging, labels, advertisements, promotional materials, and websites to intentionally mislead consumers, such as Plaintiffs and the Classes.

126. Plaintiffs and the Classes did in fact rely on these omissions and misrepresentations and purchased and used the Recalled Devices to their detriment.

127. Given the deceptive manner in which Philips advertised, represented, and otherwise promoted the Recalled Devices, Plaintiffs' and the Classes' reliance on Philips' omissions and misrepresentations was justifiable.

128. As a direct and proximate result of Philips' conduct, Plaintiffs and the Classes have suffered actual damages in that they purchased the Recalled Devices (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known of the health risks, including organ failure and cancer, associated with the use of the Recalled Devices, and (c) which did not conform to the Recalled Devices' labels, packaging, advertising, and statements.

129. Plaintiffs and the Classes seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

COUNT IV
FRAUD BY OMISSION
(on behalf of Plaintiffs and both Classes)

130. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

131. Philips concealed from and failed to disclose to Plaintiffs and the Classes that use of Recalled Devices is accompanied by a risk of adverse health effects, which does not conform to the products' labels, packaging, advertising, and statements.

132. Philips was under a duty to disclose to Plaintiffs and the Classes the true quality, characteristics, ingredients and suitability of the Recalled Devices because: (a) Philips was in a superior position to know the true state of facts about its products; (b) Philips was in a superior position to know the risks associated with the use of, characteristics of, and suitability of the Recalled Devices for use by individuals; and (c) Philips knew that Plaintiffs and the Classes could not reasonably have been expected to learn or discover prior to purchasing the Recalled Devices that there were misrepresentations and omissions by Philips in the packaging, labels, advertising, and websites regarding the health risks associated with use of these devices.

133. The facts concealed or not disclosed by Philips to Plaintiffs and the Classes were material in that a reasonable consumer would have considered them important when deciding whether to purchase the Recalled Devices.

134. Plaintiffs and the Classes justifiably relied on Philips' omissions to their detriment. The detriment is evident from the true quality, characteristics, and risk associated with the use of the Recalled Devices, which is inferior when compared to how the Recalled Devices are advertised and represented by Philips.

135. As a direct and proximate result of Philips' conduct, Plaintiffs and the Classes have suffered actual damages in that they purchased the Recalled Devices (a) that were worth less than

the price they paid, (b) which they would not have purchased at all had they known of the health risks associated with the use of the Recalled Devices, and (c) which do not conform to the Recalled Devices' labels, packaging, advertising, and statements.

136. Plaintiffs and the Classes seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws

COUNT V
NEGLIGENT MISREPRESENTATION
(on behalf of Plaintiffs and both Classes)

137. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

138. Philips had a duty to Plaintiffs and the Classes to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of the Recalled Devices.

139. Philips breached its duty to Plaintiffs and the Classes by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiffs and the Classes that did not have the qualities, characteristics, and suitability for use as advertised by Philips and by failing to promptly remove the Recalled Devices from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of the Recalled Devices.

140. Philips knew or should have known that the qualities and characteristics of the Recalled Devices were not as advertised or suitable for their intended use and were otherwise not as warranted and represented by Philips.

141. Specifically, Philips knew or should have known that: (a) the use of the Recalled Devices was accompanied by risk of adverse health effects that do not conform to the packaging and labeling; (b) the Recalled Devices were adulterated, or at risk of being adulterated, by the PE-

PUR Foam; and (c) the Recalled Devices were otherwise not as warranted and represented by Philips.

142. As a direct and proximate result of Philips' conduct, Plaintiffs and the Classes have suffered actual damages in that they purchased the Recalled Devices (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known they contained PE-PUR Foam that could cause users of the Recalled Devices to suffer adverse health effects, and (c) which do not conform to the products' labels, packaging, advertising, and statements.

143. Plaintiffs and the Classes seek actual damages, attorneys' fees, costs, and any other just and proper relief available.

COUNT VI
UNJUST ENRICHMENT
(on behalf of Plaintiffs and both Classes)

144. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

145. Plaintiffs and the Classes conferred substantial benefits on Philips through their purchase of the Recalled Devices.

146. Philips knowingly and willingly accepted and enjoyed these benefits.

147. Philips either knew or should have known that the payments rendered by Plaintiffs and the Classes were given with the expectation that the Recalled Devices would have the qualities, characteristics, and suitability for use represented and warranted by Philips.

148. As such, it would be inequitable for Philips to retain the benefit of the payments under these circumstances.

149. Philips' acceptance and retention of these benefits under the circumstances alleged herein make it inequitable for Philips to retain the benefits without payment of the value to Plaintiffs and the Classes.

150. Plaintiffs and the Classes are entitled to recover from Philips all amounts wrongfully collected and improperly retained by Philips, plus interest thereon.

151. Plaintiffs and the Classes seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

COUNT VI
PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW, 73 Pa. Stat. § 201-1, *et seq.*
(on behalf of Plaintiffs and both Classes, except for Class Members who purchased a Recalled Device for business use only)

152. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

153. Plaintiffs and Philips are persons, the Recalled Devices are goods purchased for personal, family, and/or household use, and Philips' conduct described herein is trade or commerce under the UTPCPL. 73 Pa. Stat. § 201-2(2)-(3), 201-9.2.

154. For the reasons discussed herein, Philips violated and continues to violate the UTCPL by engaging in the herein described unconscionable, deceptive, unfair acts or practices proscribed by UTCPL §§ 201-1, *et seq*.

155. Philips' acts and practices, including its material omissions, described herein, were likely to, and did in fact, deceive and mislead members of the public, including consumers acting reasonably under the circumstances, to their detriment.

156. Philips repeatedly advertised on the labels and packing for the Recalled Devices, on Philips' websites, and through national advertising campaigns, among other items, that the Recalled Devices were safe and fit for human use.

157. Philips failed to disclose the material information that the PE-PUR Foam used in the Recalled Devices, and therefore the Recalled Devices themselves, were unsafe and unfit for human use.

158. Philips' representations and omissions were material because they were likely to deceive reasonable consumers to induce them to purchase and use the Recalled Devices without being aware that the PE-PUR Foam used in the Recalled Devices, and therefore the Recalled Devices themselves, were unsafe and unfit for human use.

159. As a direct and proximate result of Philips' unfair and deceptive acts or practices, Plaintiffs and the Classes suffered damages by purchasing the Recalled Devices because they would not have purchased the Recalled Devices had they known the truth, and they received a product that was worthless because it contains unsafe PEPUR Foam which can cause a number of adverse health effects, including organ failure and cancer.

160. Philips' deceptive trade practices caused injury in fact and actual damages to Plaintiffs and members of the Classes in the form of the loss or diminishment of value of the Recalled Devices that Plaintiffs and Class Members purchased, which allowed Philips to profit at the expense of Plaintiffs and Class Members.

161. The injuries Plaintiffs and Class Members sustained were to legally protected interests.

162. The gravity of the harm of Philips' actions is significant and there is no corresponding benefit to consumers of such conduct.

163. Plaintiffs and Class Members seek relief for the injuries they have suffered as a result of Philips' unfair and deceptive acts and practices, as provided by 73 Pa. Cons. Stat. Ann. § 201-9.2 and applicable law.

COUNT VII
MEDICAL MONITORING
(on behalf of Mr. Bleakney and the User Class, except for Class Members who purchased a Recalled Device for business use only)

164. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

165. At all relevant times, the Philips designed, manufactured, assembled, inspected, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the Recalled Devices into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that used them, such as Mr. Bleakney and the User Class.

166. Philips has reported that users of the Recalled Devices face risks of serious injury from the degradation of PE-PUR Foam contained in the Recalled Devices. Degradation of PE-PUR Foam may be caused by exposure to chemical emissions from the foam material, high heat and high humidity environments in certain regions, and cleaning methods such as ozone may accelerate potential degradation.

167. When PE-PUR Foam degrades into particles that may enter the device's pathway and be ingested or inhaled by users of the devices, users face significantly increased risks of serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment.

168. The potential risks of degraded foam exposure include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects.

169. The off-gassing of chemicals from the PE-PUR Foam contained in the Recalled Devices poses risks of serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment.

170. The potential risks of exposure to off-gassing from PE-PUR Foam include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

171. The absence of visible particles does not mean that PE-PUR Foam breakdown has not already begun. Philips has reported that lab analysis of the degraded foam reveals the presence of harmful chemicals including: TDA, TDI, and DEG.[14]

172. TDI is a powerful irritant to the mucous membranes of the eyes and gastrointestinal and respiratory tracts,[15] and has been reported to cause Occupational Asthma.[16]

173. Exposure to TDA may result in ataxia, tachycardia, nausea, vomiting, convulsions, and respiratory depression.[17]

174. TDA can cause chemical cyanosis (*i.e.*, bluish discoloration of the skin) by converting hemoglobin to methemoglobin. This compound can also cause fatty degeneration of the liver.[18]

175. TDA and TDI are potential carcinogens.[19]

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[14] Philips Sleep and Respiratory Care Update; Clinical information for physicians, https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (last visited Aug. 2, 2021).

[15] The National Institute for Occupational Safety and Health (NIOSH) Current Intelligence Bulletin 53, *Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*, DHHS (NIOSH) Publication Number 90-101 (Dec. 1989); *see also* Gunnar Skarping, *et al.*, *Biological monitoring of isocyanates and related amines: Test chamber exposure of humans to toluene diisocyanate*, Dep't of Occupational and Environmental Medicine, University Hospital, S-221 85 Lund, Sweden (1990); https://greenfuture.io/sustainable-living/spray-polyurethane-foam-toxic/ (last visited Aug. 2, 2021).

[16] Bernstein, David I, *Occupational asthma: Definitions, epidemiology, causes, and risk factors*, Wolters Kluwer, https://www.uptodate.com/contents/occupational-asthma-definitions-epidemiology-causes-and-risk-factors/print (last visited Aug. 2, 2021).

[17] NIOSH, *Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*; *see also* Skarping, *Biological monitoring of isocyanates and related amines: Test chamber exposure of humans to toluene diisocyanate*; https://greenfuture.io/sustainable-living/spray-polyurethane-foam-toxic/ (last visited Aug. 2, 2021).

[18] *Id.*

[19] *Id.* ("The excess cancer risk for workers exposed to TDI and TDA has not yet been quantified, but the probability of developing cancer should be decreased by minimizing exposure.").

176. Repeated exposure to DEG has been associated with damage to the kidneys and renal failure.[20]

177. As a direct and proximate result of Philips' conduct, Mr. Bleakney and the User Class have been exposed to substantially increased risks of serious injury from off-gassing and/or degradation of PE-PUR Foam in the Recalled Devices, which is beyond normal background levels of risk.

178. As a direct and proximate result of Philips' conduct, Mr. Bleakney and the User Class have a significantly increased risk of suffering serious injury or contracting a serious latent disease, and suffering further injury at an unknown date in the future.

179. Such injuries include cancer and organ failure, among others currently unknown or just being discovered.

180. Monitoring procedures exist that makes the early detection of damage from degraded and/or off-gassed PE-PUR Foam possible.

181. These procedures are different from that normally recommended in the absence of the exposure.

182. These monitoring procedures include non-routine surveillance studies, laboratory testing, and physical examinations, and would be reasonably necessary according to contemporary scientific principles.

[20] Greg M. Landry, *Diethylene glycol-induced toxicities show marked threshold dose response in rats*, Toxicology and Applied Pharmacology 282 (2015) 244-251 ("DEG has recently been involved in several mass epidemics of renal failure and death world-wide (O'Brien et al., 1998; Schier et al., 2013). DEG poisoning clinically manifests in metabolic acidosis, hepatotoxicity, renal failure, and peripheral neuropathy, with the hallmark being acute renal failure involving proximal tubule cell necrosis and cortical degeneration (Schep et al., 2009)"); Cohen, Jeffrey A., *Demyelinating Diseases of the Peripheral Nerves*, Nerves and Nerve Injuries (2015) ("When consumed, DEG causes severe systemic and neurologic complications, including coma, seizures, peripheral neuropathy, and hepatorenal failure.").

183. Existing medical research indicates that exposure to TDI, TDA, and DEG, which Philips has found to exist in off-gassed or degraded PE-PUR Foam, can cause serious, life-threatening and permanent injuries.

184. Philips has received reports from users of the Recalled Devices of headache, upper airway irritation, cough, chest pressure and sinus infection.

185. The exposure to the defects inherent in the Recalled Devices has occurred for users, such as Mr. Bleakney and the User Class, but the full extent of the injuries will not manifest until later in their lives.

186. Thus, because of Philips' conduct, it is reasonably necessary that Mr. Bleakney and the User Class be placed under period diagnostic testing beyond that normally recommended in the absence of use of the Recalled Devices.

187. Mr. Bleakney demands judgment against Philips for medical monitoring damages to diagnose injuries caused by the Recalled Devices at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, pray for judgment against Philips as to each and every count, including:

A. An order certifying this action and the Classes requested herein as a class action, designating Plaintiffs as representatives of the Purchaser Class and Mr. Bleakney as representative of the User Class, and appointing Plaintiffs' counsel as counsel to the Classes;

B. An order declaring that Philips' actions constitute: (1) breach of express warranty; (2) breach of the implied warranty of merchantability; (3) fraudulent misrepresentation; (4) fraud

by omission; (5) negligent misrepresentation; (6) unjust enrichment; and (7) unfair and deceptive business practices in violation of Pennsylvania's UTPCPL, and that Philips is liable to Plaintiff and the Class, as described herein, for damages arising therefrom;

C. A judgment awarding Plaintiffs and members of the Classes all appropriate damages in an amount to be determined at trial;

D. A judgment awarding Mr. Bleakney and the User Class medical monitoring damages;

E. A judgment awarding Plaintiffs and the Classes prejudgment and post-judgment interest, as permitted by law;

F. A judgment awarding Plaintiffs and the Classes costs and fees, including attorneys' fees, as permitted by law; and

G. Grant such other legal, equitable or further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury for all issues so triable.

Respectfully Submitted,

Dated: August 3, 2021

/s/ Kevin W. Tucker

Kevin W. Tucker (He/Him)
PA No. 312144
Kevin J. Abramowicz (He/Him)
PA No. 320659
Chandler Steiger (She/Her)
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Counsel for Plaintiffs

VERIFICATION

I, Roxanne Bleakney, am fully familiar with the facts set forth in this Complaint and believe them to be true and correct to the best of my knowledge, information, and belief. I understand any false statements herein are made subject to the penalties of 18 Pa. C.S § 4904, relating to unsworn falsification to authorities.

Respectfully Submitted,

Dated: August 3, 2021

/s/ Roxanne Bleakney
Roxanne Bleakney
E-Signed with Permission

VERIFICATION

I, Carl Bleakney, am fully familiar with the facts set forth in this Complaint and believe them to be true and correct to the best of my knowledge, information, and belief. I understand any false statements herein are made subject to the penalties of 18 Pa. C.S § 4904, relating to unsworn falsification to authorities.

Respectfully Submitted,

Dated: August 3, 2021

/s/ Carl Bleakney
Carl Bleakney
E-Signed with Permission

EXHIBIT “A”

URGENT: Medical Device Recall

Philips Respironics
Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series Device Models

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

Dear Device Customer,

Philips Respironics is voluntarily recalling the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 1) PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during operation.

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. To date, Philips Respironics has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection. The potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects. There have been no reports of death as a result of these issues.

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator	Trilogy 100
	Trilogy 200
	Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	A-Series BiPAP Hybrid A30 (not marketed in US)
	A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	A-Series BiPAP A40
	A-Series BiPAP A30

Immediate Actions to be taken by You, the User:

1. Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks.

2. If your physician determines that you must continue using this device, **use an inline bacterial filter.** Consult your Instructions for Use for guidance on installation.

3. Register your device(s) on the recall website www.philips.com/src-update

    a. The website provides you current information on the status of the recall and how to receive permanent corrective action to address the two (2) issues.
    b. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
    c. Call 1-877-907-7508 if you cannot visit the website or do not have internet access.

Permanent Corrective Action to be Taken by the Company:
Philips is deploying a permanent corrective action to address the two (2) issues described in this Recall Notice. As part of the registration process above, you will be provided information on the next steps to implement the permanent solution.

Other Information:
If you need any further information or support concerning this recall/issue, please contact the recall support hotline or visit the website:

1-877-907-7508
www.philips.com/src-update

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or fax.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Sincerely,

Rodney Mell
Head of Quality and Regulatory
Philips Respironics - Sleep & Respiratory Care

URGENT: Medical Device Recall

Philips Respironics
CPAP and Bi-Level PAP Devices

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

Dear Device Customer,

Philips Respironics is voluntarily recalling the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 1) PE-PUR foam may degrade into particles which may enter the device's the air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during initial operation and may possibly continue throughout the device's useful life.

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. To date, Philips Respironics has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection. The potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects. There have been no reports of death as a result of these issues.

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Emergency Use Authorization)
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne ASV4
	C-Series ASV
	C-Series S/T and AVAPS
	OmniLab Advanced+
Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

Immediate Actions to be taken by You, the User:

1. Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in this letter.

2. Register your device on the recall website www.philips.com/src-updates
    d. The website provides you current information on the status of the recall and how to receive permanent corrective action to address the two (2) issues.
    e. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
    f. Call 1-877-907-7508 if you cannot visit the website or do not have internet access.

Permanent Corrective Action to be Taken by the Company:
Philips is deploying a permanent corrective action to address the two (2) issues described in this Recall Notice. As part of the registration process above, you will be provided information on the next steps to implement the permanent solution.

Other Information:
If you need any further information or support concerning this issue, please contact the recall support hotline or visit the website:

1-877-907-7508
www.philips.com/src-update

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail or fax.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Sincerely,

Rodney Mell
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